APHIOS CORPORATION (formerly BioEng, Inc.)

Reducing Viral Contamination in Donated Blood

This ATP project with Aphios Corporation, a small Massachusetts company founded in 1988 as BioEng, developed technology to improve the quality of donated blood in the United States. If the technology is fully developed and widely applied, substantial benefits would accrue to patients. The transfused blood or other therapeutic substances they receive would essentially be free of hepatitis virus, human immunodeficiency virus (HIV, which causes acquired immunodeficiency syndrome, or AIDS), and other viruses that may contaminate vaccines, donated blood, blood-related products, medical instruments, and recombinant-DNA proteins.

COMPOSITE PERFORMANCE SCORE
(based on a four star rating)

no stars

Solving the Problem of Contaminated Blood

Several sterilization procedures using heat, a chemical, or ultraviolet radiation are already in use, but each method has drawbacks: it may leave unsafe levels of some viruses, be very costly, or damage the blood or plasma. The Aphios sterilization technology, called

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critical-fluid inactivation (CFI), uses a fluid such as carbon dioxide that is raised above its critical temperature and pressure. Above these levels, the substance cannot be liquefied. In laboratory tests, such fluids exhibit a combination of liquid and gaseous properties, and they have been found to effectively inactivate prototypical viruses. Critical-fluid viral inactivation uses low temperatures and short process times, so it has a minimal impact on blood and blood-related products. And, at an estimated cost of about $1 per liter, it is much less expensive than existing technology.

Overcoming Parvovirus

The procedure Aphios developed during the ATP project has been able to achieve 99.9999 percent inactivation or more for most viruses in 20 seconds (99.99 percent inactivation by an individual viral inactivation technique is considered acceptable). The most difficult challenge has been parvovirus.

Parvovirus B19 in blood and blood products has proven difficult to inactivate, not only by the CFI process but by others as well. The virus is relatively benign for patients with healthy immune systems. But it can have serious consequences for those with weakened immune systems, as well as for pregnant women and persons with sickle cell anemia. The current Aphios procedure has achieved 90 percent inactivation of this virus. The

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company is working on a five-step procedure that is expected to achieve better than 99.99 percent inactivation.

PROJECT HIGHLIGHTS

Project:
To develop a critical-fluid viral inactivation process to protect the nation's supply of donated blood and blood-

Duration: 7/1/1992 — 6/30/1995
ATP Number: 91-01-0135
Funding (in thousands):

Total $3,000

Accomplishments:
Aphios developed a procedure using critical fluids to inactivate viruses in blood and established that the process is applicable to a large number of viruses, although with different levels of effectiveness. The following achievements indicate technical progress by the company, which:

- applied for a patent ("Viral Inactivation Method and Apparatus") on technology related to the ATP project;

- presented two papers at conferences on blood-safety issues;

- executed a letter of intent with the Northeast Region of the American Red Cross to develop and field-test a virus inactivation prototype for individual units of blood; and

- submitted a proposal to a consortium of companies to evaluate the viral inactivation technology for use in developing products and processes.

Commercialization Status:
Aphios has not commercialized the process yet. The firm has been negotiating with a health care company interested in sponsoring further development and commercialization of the technology. Some early knowledge benefits have emerged from the project via patent disclosures and scientific papers.

Outlook:
Commercialization may occur after more R&D work, primarily on the inactivation of parvovirus. There has been evidence of interest in the technology by the health-care community in general and by the American Red Cross in particular. Benefits are expected to accrue to society if the development of the technology can be completed successfully. However, given the company's financial difficulties, the outlook at this time is uncertain.

Composite Performance Score: no stars

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Number of Employees: 3 at project start, 17 at the end of 1997

The blood industry has established an extremely high standard for new technologies. Therefore, commercial deployment of the Aphios technology will be much easier if the company can demonstrate that its technology can inactivate parvovirus to an acceptable degree. If it succeeds with this task, Aphios will seek to join a larger pharmaceutical company or consortium to further develop and commercialize the process, with substantial investment coming from these sources.

Without the ATP funds, Aphios officials say, the company would not have conducted the project.

In 1998, Aphios sought an arrangement with a consortium of five pharmaceutical companies to complete development of the CFI process.

If a company wishes to commercialize a product for use with donated human blood, it must deal with the American Red Cross (ARC), the source of most blood products used in clinics and hospitals in the United States. Aphios has signed a letter of intent with the viral inactivation prototype for individual units of blood and is seeking funding for the project.

Health Benefits to Patients and Those Close to Them

If the technology is fully developed and commercialized, benefits are expected to accrue to users of blood and blood-derived products that can be made virus-free with the Aphios technology. Reducing the spread of viral disease is expected to generate large health-cost savings and related benefits to the United States. Users will also benefit if the process based on the new technology is, as expected, less costly than current decontamination procedures. Economic benefits might also extend to people who avoid viral disease because

users of blood or blood-derived products decontaminated with the Aphios technology do not become infected and spread the disease.

Without the ATP funds, Aphios officials say, the company would not have conducted the project. Moreover, it would have been impossible for this small company to attract the interest of the health care company or the American Red Cross.

As this report was going to press in late 1998, it was learned that the company had reduced staff and was experiencing financial distress.